UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,914	09/30/2003	Bevil J. Hogg	5236-000452	8982

28997 7590 08/27/2009

HARNESS, DICKEY, & PIERCE, P.L.C
7700 Bonhomme, Suite 400
ST. LOUIS, MO 63105

EXAMINER	
NGUYEN, HUONG Q	

ART UNIT	PAPER NUMBER
3736	

MAIL DATE	DELIVERY MODE
08/27/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/674,914
Filing Date: September 30, 2003
Appellant(s): HOGG ET AL.

Kevin Pumm
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 5/12/2009 appealing from the Office action mailed 12/10/2008.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

WO 00/07641	Stereotaxis	02-17-2000
6266551	Osadchy et al	07-24-2001
6401723	Garibaldi et al	06-11-2002
6237604	Burnside et al	05-29-2001

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

1. **Claim 1-6, 8-9, 11-17, and 52** are rejected under 35 U.S.C. 103(a) as being unpatentable over Stereotaxis (WO 00/07641) in view of Osadchy et al (US Pat No. 6266551).

2. In regards to **Claim 1**, Stereotaxis discloses a medical navigation system for controlling the distal end of an elongate flexible medical device in a subject's body, the system comprising:

an elongate flexible medical device 24 having on its distal end 76 one or more magnetically responsive elements 78 that respond to an externally applied magnetic field to change the direction of the distal end of the medical device, best seen in Figure 1-3 (p.3: 17-20; p.8: 33-37; p.9: 4-11);

a navigation device 22 configured to create a magnetic field used to steer the elongate flexible medical device, and to determine, as a function of the physical and geometric properties (p.5: 1-5; p.8: 37-39; p.9: 1-17) actuation control variables for an applied actuation consisting essentially of an external magnetic field, where the navigation device determines and applies an

appropriate magnetic field direction for actuating the distal end of an elongate flexible medical device and thereby changing its orientation (p.5: 6-17, 31-38; p.6: 23-27; p.7: 6-26; p.8: 7-29);

an electronic interface 36, 38, 40 for selectively operating the navigation device for selectively controlling the orientation of the distal end of the elongate flexible medical device, the electronic interface comprising a processor in computer 26 and including at least one software program, wherein the interface provides actuation instructions to the navigation device for controlling the distal end of the device (p.4: 26-30; p.5: 6-10; p.6: 1-15, 24-40; p.7: 1-26), which instructions take into account the physical and geometric properties of the elongate medical device (p.5: 1-5; p.8: 37-39; p.9: 1-17).

3. However, Stereotaxis does not disclose an electronic identification device on the elongate medical device that includes information on the physical and geometric properties of the elongate medical device including the number of magnetically responsive elements and spacing therebetween, and identification information that provides for elongate flexible medical device identification, wherein navigation of the device is only enabled in the presence of the electronic identification device.

4. Osadchy et al disclose a catheter system comprising an electronic identification device 90 on an elongate flexible medical device 20 that includes information on the physical and geometric properties of the elongate medical device including the number of magnetically responsive elements 60, 62, 64 and spacing therebetween, i.e. d_y and d_z (Col.11: 1-22, 26-31, 65-67; Col.12: 1-16), best seen in Figure 1-2, wherein the number of magnetically responsive elements and the spacing therebetween are used to determine calibration correction data (Col.15: 17-21, 53-58) to enable proper determination by computer 36 of the actual position and

orientation of the distal tip 26 of the elongate medical device in the body (Col.15: 26-29, 64-67; Col.16: 1-13, 52-55) and wherein said unique calibration correction data for said elongate medical device is stored on the electronic identification device 90 (Col.16: 26-43). Osadchy et al also disclose an electronic interface 36 comprising a processor 40 and includes at least one software program that enables use and thus navigation control of the elongate medical device only in the presence of the electronic identification device (Col.5: 60-62; Col.17: 33-46).

5. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Stereotaxis to include an electronic identification device on the elongate medical device that includes information about the elongate medical device such as the physical and geometric properties of the elongate medical device including the number of magnetically responsive elements and spacing therebetween, and the instructions to the navigation device take into account the number of magnetically responsive elements and spacing therebetween obtained from the electronic identification device, and wherein navigation of the device is only enabled in the presence of the electronic identification device, as taught by Osadchy et al, to enable accurate determination of the position and orientation of the elongate medical device for proper navigation by taking into account the positioning of the magnetically responsive elements, and to ensure that such pertinent identifying information is provided for each particular elongate medical device before use for improved navigation and safety.

6. In regards to **Claims 2**, Osadchy et al disclose the electronic identification device 90 includes a memory (Col.16: 37-43), and wherein the interface 36 includes a reader for reading the memory (Col.16: 52-55).

7. In regards to **Claims 3**, Osadchy et al disclose the electronic identification device 90 includes a memory unit (Col.16: 37-43) and a processing unit that communicates with the interface for transferring information (Col.7: 62-67).

8. In regard to **Claims 4-5 and 8-9**, Osadchy et al disclose the memory contains unique identifying information about the type of device, and wherein the interface includes a database of the unique identifying information of the type of devices with which the interface is intended to operate (Col.17: 33-46).

9. In regards to **Claim 6**, Osadchy et al disclose the electronic identification device 90 is a circuit, i.e. microcircuit best seen in Figure 5 that is connected to the interface 36.

10. In regards to **Claim 11**, Stereotaxis in combination with Osadchy et al disclose the interface includes a plurality of programs, each adapted for use with a different type of elongate flexible medical device, each program operating only when an electronic identification device for the particular type of elongate flexible medical device is present (Osadchy et al Col.5: 50-62).

11. In regards to **Claim 12**, Osadchy et al disclose the electronic identification device 90 includes an integrated circuit.

12. In regards to **Claim 13**, Osadchy et al disclose the interface 36 operates on the electronic identification device 90 to prevent reuse of the elongate flexible medical device (Col.18: 46-55).

13. In regards to **Claim 14**, Osadchy et al disclose the interface 36 tracks elapsed time of use of the identified elongate flexible medical device 20 and invalidates use of the identified elongate flexible medical device when the elapsed time exceeds a pre-defined limit (Col.17: 55-65; Col.18: 46-55).

14. In regards to **Claim 15**, Osadchy et al disclose the processing unit operates on the memory unit to prevent reuse of the elongate flexible medical device (Col.18: 9-55).

15. In regards to **Claim 16**, Osadchy et al disclose the electronic identification device 90 includes memory, and wherein the interface adds to or deletes information stored on the memory to prevent reuse of the device (Col.18: 9-55).

16. In regards to **Claim 17**, Stereotaxis discloses the at least one software program controls navigation by employing a computational model of flexible device physics.

17. In regards to **Claim 52**, Stereotaxis discloses a medical navigation system for controlling the distal end of an elongate medical device in the body of the patient comprising:

an elongate flexible medical device 24 including at least one magnet 78, best seen in Figure 1-3;

a control system 22 for controlling the position and/or orientation of the distal end 76 of the elongate medical device (p.5: 6-17, 31-38; p.6: 23-27; p.7: 6-26; p.8: 7-29); wherein the control system is a magnetic navigation system for controlling the elongate medical device that includes at least one magnet and uses information on the physical and geometric properties of the elongate medical device for navigational control of the device (p. 7: 15-26; p.8: 37-39; p.9: 1-17);

an interface 36, 38, 40 for accepting inputs from the user to cause the control system to selectively change the position and/or orientation of the elongate medical device (p.4: 26-30; p.5: 6-10; p.6: 1-15, 24-40; p.7: 1-26); the interface sending instructions to the control system dependent in part upon the medical device's physical and geometric property information, wherein the physical and geometric properties of the device are used in navigational control algorithms for guiding the device (p. 7: 15-26; p.8: 37-39; p.9: 1-17).

18. However, Stereotaxis does not disclose a memory device provided on the flexible medical device that includes stored information on the physical and geometric properties of the elongate medical device such as at least a magnet dimension or a magnet type that are relevant to navigational control of the device. Osadchy et al disclose a catheter system comprising a memory device 90 on an elongate flexible medical device 20 that includes information on the physical and geometric properties of the elongate medical device including the number of magnetically responsive elements 60, 62, 64 and magnet dimension or spacing therebetween, i.e. d_y and d_z (Col.11: 1-22, 26-31, 65-67; Col.12: 1-16), best seen in Figure 1-2, wherein the number of magnetically responsive elements and the spacing therebetween are used to determine calibration correction data (Col.15: 17-21, 53-58) to enable proper determination by computer 36

of the actual position and orientation of the distal tip 26 of the elongate medical device in the body (Col.15: 26-29, 64-67; Col.16: 1-13, 52-55) and wherein said unique calibration correction data for said elongate medical device is stored on the memory device 90 (Col.16: 26-43).

19. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Stereotaxis to include a memory device on the flexible medical device that includes information about the medical device such as the physical and geometric properties of the elongate medical device including the number of magnetically responsive elements and magnet dimension, and the instructions to the control system are dependent in part upon the number of magnetically responsive elements and magnet dimension obtained from the memory device, as taught by Osadchy et al, to enable accurate determination of the position and orientation of the flexible medical device for proper navigation by taking into account the positioning of the magnets and thus their dimensions, and to ensure that such pertinent identifying information is provided for each particular elongate medical device before use for improved navigation and safety.

20. **Claim 10** is rejected under 35 U.S.C. 103(a) as being obvious over Stereotaxis in view of Osadchy et al, further in view of Burnside et al (US Pat No. 6237604).

21. Stereotaxis in combination with Osadchy et al in the manner above disclose the electronic identification device above that transmits a signal to the interface above but do not disclose said device is RF circuit. Burnside et al teach the use of an RF circuit to effectively transmit a signal (abst). Therefore, it would have been obvious to one of ordinary skill in the art at the time the

invention was made to make the circuit of Stereotaxis as modified by Osadchy et al a RF circuit as taught by Burn as an effective means for such.

22. **Claims 38-40** are rejected under 35 U.S.C. 103(a) as being unpatentable over Stereotaxis in view of Garibaldi et al (US Pat No. 6401723), further in view of Osadchy et al.

23. In regards to **Claim 38**, Stereotaxis discloses a medical navigation system for controlling the distal end of an elongate medical device in the body of the patient comprising:

an elongate flexible medical device 24, best seen in Figure 1;

a control system 22, 26 for controlling the position and/or orientation of the distal end 76 of the elongate medical device (p.5: 6-17, 31-38; p.6: 23-27; p.7: 6-26; p.8: 7-29), where an elastic property of the device is used in navigational control algorithms for guiding the device, i.e. the stiffness or elasticity of the device must be taken into account when determining the magnetic field intensity required to control the distal end of the device (p.7: 15-26; p.8: 37-39; p.9: 1-17);

an interface 36, 38, 40 for accepting inputs from the user to cause the control system to selectively change the position and/or orientation of the elongate medical device (p.4: 26-30; p.5: 6-10; p.6: 1-15, 24-40; p.7: 1-26); the interface sending instructions to the control system dependent in part upon the medical device's physical and geometric property information, including the elastic property of the device obtained from the memory device as explained above, wherein the physical and geometric properties of the device are used in navigational control algorithms for guiding the device (p.5: 1-5; p.8: 37-39; p.9: 1-17).

24. However, Stereotaxis does not disclose one or more cross sectional areas of the elongate device used in navigational control algorithms for guiding the device. Garibaldi et al teach that the cross sectional area of the coil wire of an analogous elongate medical device is directly proportional to the magnetic moment of the coil, which is then directly proportional to the magnetic torque applied to the distal end of the elongate medical device (Col.4: 36-42). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Stereotaxis such that one or more cross sectional areas of the elongate device are used in navigational control algorithms for guiding the device as taught by Garibaldi et al to effectively take into account the effect of the cross sectional area on the magnetic torque of the elongate medical device.

25. However, Stereotaxis and Garibaldi et al do not disclose a memory device provided on the flexible medical device that includes the information on the physical and geometric properties including one or more cross sectional areas of the elongate device and an elastic property of the elongate medical device that are relevant to navigational control of the device as described above. Osadchy et al disclose a catheter system comprising a memory device 90 on an elongate flexible medical device 20 that includes information on the physical and geometric properties of the medical device, i.e. the position and orientation of distal tip 26 relative to coils 60, 62, 64 as well as information regarding the position of said coils or the gains of the coils (Col.2: 1-45, 65-66; Col.3: 1-4; Col.7: 21-29), to provide effective proper medical device identification before use (Col.17: 34-46).

26. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Stereotaxis as modified by Garibaldi et al to

include a memory device provided on the flexible medical device that includes the information on the physical and geometric properties such as one or more cross sectional areas of the elongate device and an elastic property of the elongate medical device that are relevant to navigational control of the device as described above, as taught by Osadchy et al, to ensure that such pertinent identifying information is provided for each particular flexible medical device before use for improved navigation and safety.

27. In regards to **Claim 39**, Stereotaxis discloses the at least one software program controls navigation by employing a computational model of flexible device physics.

28. In regards to **Claim 40**, Stereotaxis in combination with Osadchy et al disclose the memory device includes storing unique device identification information for the elongate flexible medical device, and wherein the interface includes a database of unique device identification information and corresponding device properties, and wherein the instructions sent to the control system take into account the device properties determined from the database (Osadchy et al Col.17: 33-46).

(10) Response to Argument

Appellant’s arguments filed 5/12/2009 have been fully considered but they are not persuasive. The Examiner respectfully maintains all grounds of rejection, noting the following in response to Appellant's arguments:

Appellant contends that an artisan considering Osadchy et al's teaching of a calibration offset would not have resulted, in combination with Stereotaxis, a device that stores the number of magnetically responsive elements and spacing therebetween for use in determining navigation variables.

However, it is noted that the calibration offset of Osadchy et al necessarily takes into account the number of magnetically responsive elements and spacing therebetween. Distance L, best seen in Figure 2, is defined as the distance along the Z-axis from the central axis 68 of coil 62 to tip 26 (Col.11: 26-31), wherein the position of the central axis is dependent upon the number of magnetically responsive elements, i.e. coils (Col.4: 16-28), and spacing therebetween. Osadchy et al discloses that the device may comprise a single coil or two or more such coils (Col.11: 19-22). In the instant case, three coils 60, 62, and 64 are present, as best seen in Figure 2, which are taken into account in the determination of distance L from the central axis. The number of magnetically responsive elements and spacing therebetween also determine the distances d_y and $d_{z,}$ also best seen in Figure 2, which are also used to determine the calibration offset (Col.15: 17-21, 53-58).

Therefore, it is respectfully submitted that because Osadchy et al teach the advantages of taking into account the number of magnetically responsive elements and spacing therebetween (for example, when using a device of Stereotaxis comprising a plurality of spaced magnets - p.9:

6-7) to determine the calibration offset to properly determine the actual position and orientation of the distal tip 26 of the elongate medial device for proper navigation, the combination of Stereotaxis and Osadchy et al make obvious the invention as claimed by predictably resulting in a medical navigation system that includes information on the number of magnetically responsive elements and spacing therebetween for use in determining navigation variables. The same reasoning is respectfully applied to Claim 52, wherein magnet dimension is defined to include the spacing between the magnetically responsive elements, as elaborated above.

Regarding Claim 38, Appellant contends that Garibaldi et al constitutes 102(e) art and is not available as prior art under 35 USC § 103(c). However, it is noted that Garibaldi et al has a publication date of June 11, 2002. The instant application has an effective filing date of September 30, 2002. June 11, 2002 is earlier than September 30, 2002. Thus Garibaldi et al constitutes 102(a) art, which is not excluded under 35 USC § 103(c).

Therefore, it is respectfully maintained that the combination of Stereotaxis, Garibaldi et al, and Osadchy et al as combined the manner above make obvious the invention as claimed in Claims 38-40, wherein Garibaldi et al teach the advantages of including information on one or more cross sectional areas of the elongate device for use in determining navigation variables. It is noted that Stereotaxis already teaches taking into account the stiffness or an elastic property of the device (p.8: 37-39; p.9: 1-17).

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/H. N./

Examiner, Art Unit 3736

Conferees:

/Max Hindenburg/

Supervisory Patent Examiner, Art Unit 3736

/Angela Sykes/

Supervisory Patent Examiner, Art Unit 3762